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November 19, 2004

Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810), Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Brush Pkwy. College Park, MD 20740

Section 403(r) (6) Notification

Dear Sir or Madam:

In accordance with the requirement of section 403(r) (6) of the Federal Food, Drug and Cosmetic Act, **Leiner Health Products** notifies the FDA that it has begun using the following phrase and statement:

Helps Support Your Body through Natural Changes

Isoflavones are phytoestrogens, nutrients from plants with estrogen-like chemical structures. Studies show that isoflavones may help maintain healthy bones, already healthy cholesterol levels and good cardiovascular health. Studies have also shown that soy isoflavones may benefit men's health by contributing to good prostate health. Calcium 600 mg + Soy Isoflavones is an ideal complex for bone health. Regular exercise and a healthful diet with adequate calcium are essential in achieving peak bone mass in teenagers and young adults and maintaining bone health during adulthood. Individuals who do not store enough calcium throughout their lives have an increased risk for developing osteoporosis. Vitamin D assists in the absorption of calcium.

Soy isoflavones are natural plant nutrients that help your body support bone health. Soy isoflavones also help promote good menopausal health.

on the following product:

Your Life® Calcium 600 mg with Soy Isoflavones & Vitamin D

Very truly yours,

Leiner Health Products

Kristi Ansnes

Regulatory Affairs Associate

97S 0162 LET 14/94/1



Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810), Center for Food Safety and Applied Nutrition Food and Drug Administration (Continued)

The following brands also use the above statement:

Albertson's BI-MART

BIO BALANCE® COUNCIL LABS®

CVS® ECKERD® equate® Hannaford® HealthLine health PRIDE Kash n' Karry

KIRKLAND Signature™

Kroger®
Longs
MARC'S
Member's Mark
MEIJER™

Nature's Origin®

NATURE'S VALLEY™

NATURITE®

NUTRA CHOICE

NUTRI-BLEND

Osco®

PHARMACIST FORMULA®

BODYCOLOGYTM

SAFEWAY SELECT™

Sav•on[™]
Shaw's
ShopKo®
Spring Valley®
TARGET®

TOP CARE® TRUNATURE®

Wegmans®